REMARKS

Claims 1-39 are pending in the application. Claims 19-37 are withdrawn from consideration.

A spray pump's performance is characterized in terms of its emitted spray pattern, plume geometry, and/or droplet size distribution. These parameters are known to be affected by the means in which the spray pump is actuated. For example, slow actuation will likely cause poor atomization, producing a stream-like flow. Fast actuation will likely produce too fine a spray, leading to poor absorption in the nasal mucosa and unwanted inhalation and deposition of the droplets in the throat and lungs. Testing the delivery of spray devices may be done to verify the spray device actuates the drug within the proper criteria, but operator actuation variability may adversely affect test results.

An embodiment of the principles of the present invention includes an assembly that provides information about operation of a spray device. The assembly includes an adapter assembly configured to be coupled to a movable part of the spray device. In the case of a nasal spray, the movable part is the nasal tip and, in the case of a metered dose inhaler (MDI), the movable part is the canister containing the drug. The assembly also includes a mounting assembly configured to be coupled to a stationary part of the spray device. In the case of the nasal spray device, the stationary part is the bottle containing the drug and, in the case of the MDI, the stationary part is the mouthpiece. The assembly also includes a transducer, coupled to the mounting assembly or the adapter assembly. The assembly also includes a linkage that is adapted to extend between the mounting assembly and the adapter assembly. The linkage is in operational relationship with the transducer to enable the transducer to indicate a mechanical relationship between the movable and stationary parts of the spray device corresponding to the operation of the spray device.

Fig. 3 is an illustration of an example assembly adapted to work with a spray device 100. In particular, the assembly is adapted to indicate a mechanical relationship between a movable part 305 and a stationary part of the spray device 100 corresponding to operation of the spray device 100.

Components that are connected to the spray device 100 include (a) an adapter assembly 315a, which connects to the movable part 305, (b) a mounting assembly 320a, which connects to the spray device 100, (c) a transducer 335, which is connected to the mounting assembly 320a in this embodiment but may be connected to the adapter assembly 315a in other embodiments, and (d) a linkage 330, that is adapted to extend between the mounting assembly 320a and adapter assembly 315a. The linkage 330 is in operational relationship with the transducer 335 to enable the transducer to indicate the mechanical relationship between the movable part and the stationary part of the spray device corresponding to operation of the spray device.

In operation, a person operates the spray device in a typical manner by placing the fingers on the adapter assembly 315a and drawing it toward the mounting assembly 320a to cause the movable part 305 to move. When the spray device 100 is actuated, the linkage 330 causes the transducer 335 to change its state. A change in state of the transducer 335 causes the transducer output to change state in a proportional manner.

Fig. 4 illustrates an assembly applied to a metered-dose inhaler (MDI) 400. In the case of the MDI, a pressurized canister 405 is the movable part, and a mouthpiece 410 is the stationary part. A person's hand squeezes the pressurized canister 405 toward the mouthpiece 410 to actuate the MDI and cause a "shot" to be expelled from the MDI 400. Similar to its usage with the spray bottle 100, the linkage 330 extends between the adapter assembly 315b and mounting assembly 320b. The linkage 330 causes the transducer 335 to change states in a proportional manner.

Fig. 6 illustrates an embodiment of an assembly 600 that employs a bearing 610 and shaft 605 assembly that substantially maintains alignment between the adapter assembly 315c and the mounting assembly 320c. The linkage 330 is extended through the shaft 605 and connects to a shaft head 615 by extending through a center hole in the shaft head 615.

Because the linkage extends between the mounting assembly and the adapter assembly in the embodiments of the invention, parameters for position, velocity, and acceleration can be obtained that are representative of motion of the movable part 305 with respect to the stationary part 310 in a typical spray device 100, 400 by in vitro actuation or automated actuation (see Fig. 13).

Rejection of Claims Under 35 U.S.C. § 102

Claims 1, 4, 7, 11, 14, 15, 17 and 18 were rejected under 35 USC 102(b) as being anticipated by Wolf (US6148815). The rejection is respectfully traversed.

Wolf discloses an electronic medication chronolog device. Wolf describes a chronolog apparatus 1200 attached to adaptable housing 1210 (Figure 13). The device includes a strain gauge sensing arm 1555 (Figure 15a) which is attached to computing equipment and extends through a hole in a side of an actuator housing for engaging a portion of a vial/canister next to the valve stem.

The sensing arm 1555 includes a contactor 1630. When the vial/canister is compressed, a surface 1640 of the vial/canister makes physical contact with the contactor 1630 in the sensing arm 1555. The sensing arm senses only the vial/canister's contact and cessation of contact with the contactor 1630 and signals the computing equipment. Such sensing arm 1555 is not a "linkage" since it is free at one end and provides no linking function. (col. 18, lines 27-47; Figures 15a; 15b; 16) Therefore, Wolf fails to teach "a linkage adapted to extend between the mounting assembly and the adapter assembly," as required by claim 1.

Regarding claims 15 and 17, the Office Action stated that Wolf discloses calculating parameters (position, velocity or acceleration - claim 15; maximum position displacement, hold time, maximum actuation velocity, maximum return velocity, maximum actuation acceleration, and maximum return acceleration – claim 17) referring to Wolf sections column 22, lines 60-63 and column 23, lines 20-27. Applicants disagree.

The sections of Wolf cited in the rejection of claims 15 and 17 do not refer to the parameters recited in claims 15 and 17. The strain gauge sensing arm in Wolf allows the apparatus to detect only that the vial/canister has been compressed and, therefore, the presumed start of the medication delivery process. While Figs. 19a through 19e show graphic representations of signals generated by the strain gauge sensing arm, there is no attempt or even suggestion in Wolf to derive or calculate the parameters of interest in claims 15 and 17.

Accordingly, the subject-matter of claims 1, 4, 7, 11, 14, 15, 17 and 18 are not anticipated by Wolf. Reconsideration of the rejection under 35 USC 102(b) is respectfully requested.

Rejection of Claims Under 35 U.S.C. § 103

Claims 2, 3, 8 and 9 were rejected under 35 USC 103(a) as being unpatentable over Wolf in view of Roberts (US5579659). Claims 10, 12, 13, 38 and 39 were rejected under 35 USC 103(a) as being unpatentable over Wolf in view of Barger et al. (US2005/0016527). The rejections are respectfully traversed.

Regarding claim 9, the Office Action stated that Roberts discloses a linkage that is a spring loaded wire integrally associated with the potentiometer, with reference made to Roberts col. 4, lines 3-14. At the cited section, Roberts discloses a sensing rod 84 that extends from a potentiometer and abuts a stop 86 (Figure 3). However, such a sensing rod clearly does not constitute a "linkage" since it is free at one end and therefore does not link anything.

For at least the above-noted reasons regarding the rejection of base claim 1, respective dependent claims 2, 3, 8-10, 12, 13, 38 and 39 are believed to be patentable over Wolf alone or taken with Roberts or Barger et al.

CONCLUSION

In view of the above remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue.

Respectfully submitted,

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